# UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

# [X] QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended <u>September 30, 2007</u>

or

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES
EXCHANGE ACT OF 1934

For the transition period from \_\_\_\_\_to \_\_\_\_

**Commission File Number: 000-26658** 



# PHARMACYCLICS, INC.

(Exact name of registrant as specified in its charter)

#### **Delaware**

#### 94-3148201

(State or other jurisdiction of incorporation or organization)

(IRS Employer Identification Number)

# 995 E. Arques Avenue Sunnyvale, California 94085-4521

(Address of principal executive offices including zip code)

#### (408) 774-0330

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  $\square$  No  $\square$ 

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer □ Accelerated filer ☑ Non-accelerated filer □

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  $\square$  No  $\square$ 

As of October 31, 2007, there were 25,968,189 shares of the registrant's Common Stock, par value \$0.0001 per share, outstanding.

This quarterly report on Form 10-Q consists of 19 pages of which this is page 1. The Exhibits Index page immediately follows page 18.

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## Item 1. Financial Statements

# PHARMACYCLICS, INC. (a development stage enterprise) CONDENSED BALANCE SHEETS (unaudited; in thousands)

		September 30, 2007		June 30, 2007
ASSETS	_			
Current assets:				
Cash and cash equivalents		8,419	\$	11,941
Marketable securities		23,904		26,821
Prepaid expenses and other current assets	_	1,058	_	961
Total current assets		33,381		39,723
Property and equipment, net		760 523		849
Other assets	_		_	523
	\$_	34,664	\$_	41,095
LIABILITIES AND STOCKHOLDERS' EQUITY  Current liabilities:  Accounts payable	-	1,429 912	\$	1,426 1,189
Total current liabilities		2,341		2,615
Deferred rent	-	78	_	79
Total liabilities	_	2,419		2,694
Stockholders' equity:				
Common stock		3		3
Additional paid-in capital		354,237		353,560
Accumulated other comprehensive loss		(12)		(9)
Deficit accumulated during development stage	_	(321,983)	_	(315,153)
Total stockholders' equity	_	32,245		38,401
	\$_	34,664	\$	41,095

The accompanying notes are an integral part of these condensed financial statements.

# PHARMACYCLICS, INC. (a development stage enterprise) CONDENSED STATEMENTS OF OPERATIONS (unaudited; in thousands, except per share data)

	-	Three Months Ended September 30, 2007 2006				Period From Inception (April 19, 1991) through September 30,
	-	2007	-	2006	•	2007
Revenues:						
License and milestone revenues	\$		\$		\$	7,855
Contract and grant revenues				19		6,154
Total revenues	-		-	19		14,009
Operating expenses:						
Research and development*		5,240		5,078		298,982
General and administrative*		2,067		1,924		70,876
Purchased in-process research and development	_		_			6,647
Total operating expenses	_	7,307	_	7,002		376,505
Loss from operations		(7,307)		(6,983)		(362,496)
Interest and other income, net	_	477	_	492		40,513
Net loss	\$_	(6,830)	\$_	(6,491)	\$	(321,983)
Basic and diluted net loss per share	\$_	(0.26)	\$_	(0.31)		
Shares used to compute basic and diluted net loss per share	=	25,968	=	20,968		
* Includes non-cash share-based compensation of the following:	ė	200	¢	460	¢.	5 202
Research and development	\$	308 369	\$	468 285	\$	5,323 5,617

The accompanying notes are an integral part of these condensed financial statements.

# PHARMACYCLICS, INC. (a development stage enterprise) CONDENSED STATEMENTS OF CASH FLOWS (unaudited; in thousands)

**Period From** 

		Months Ended	Inception (April 19, 1991) through September 30,
	2007	2006	2007
Cash flows from operating activities:			
Net loss	\$ (6,830)	\$ (6,491)	\$ (321,983)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	92	122	14,729
Amortization of premium/discount on marketable securities, net	(56)	(38)	146
Purchased in-process research and development			4,500
Share-based compensation expense	677	753	10,940
Gain on sale of marketable securities	(9)		49
Write-down of fixed assets			381
Changes in assets and liabilities:			
Prepaid expenses and other assets	(97)	81	(1,581)
Accounts payable	3	(229)	1,429
Accrued liabilities	(277)	(164)	912
Deferred rent	(1)	(2)	78
Net cash used in operating activities	(6,498)	(5,968)	(290,400)
Cash flows from investing activities:			
Purchase of property and equipment	(3)	(269)	(12,101)
Proceeds from sale of property and equipment			112
Purchases of marketable securities		(948)	(524,100)
Proceeds from maturities and sales of marketable securities	2,979		499,989
Net cash provided by (used in) investing activities	2,976	(1,217)	(36,100)
Cash flows from financing activities:			
Issuance of common stock, net of issuance costs			308,855
Exercise of stock options		360	6,431
Proceeds from notes payable			3,000
Issuance of convertible preferred stock, net of issuance costs			20,514
Payments under capital lease obligations			(3,881)
Net cash provided by financing activities		360	334,919
Increase (decrease) in cash and cash equivalents	(3,522)	(6,825)	8,419
Cash and cash equivalents at beginning of period		22,283	
Cash and cash equivalents at end of period	\$ 8,419	\$ 15,458	\$ 8,419

The accompanying notes are an integral part of these condensed financial statements.

# PHARMACYCLICS, INC. (a development stage enterprise) NOTES TO CONDENSED FINANCIAL STATEMENTS

### Note 1 - Summary of Significant Accounting Policies

#### **Basis of Presentation**

The accompanying interim condensed financial statements have been prepared by Pharmacyclics, Inc. (the company or Pharmacyclics), without audit, in accordance with the instructions to Form 10-Q and, therefore, do not necessarily include all information and footnotes necessary for a fair statement of its financial position, results of operations and cash flows in accordance with accounting principles generally accepted in the United States. The balance sheet at June 30, 2007 is derived from the audited balance sheet at that date which is not presented herein.

In the opinion of management, the unaudited financial information for the interim periods presented reflects all adjustments, which are only normal and recurring, necessary for a fair statement of results of operations, financial position and cash flows. These condensed financial statements should be read in conjunction with the financial statements included in the company's Annual Report on Form 10-K for the fiscal year ended June 30, 2007. Operating results for interim periods are not necessarily indicative of operating results for an entire fiscal year.

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts and the disclosure of contingent amounts in the company's financial statements and the accompanying notes. Actual results could differ from those estimates.

#### Note 2 - Basic and Diluted Net Loss Per Share

Basic net loss per share is computed using the weighted average number of common shares outstanding during the period. Diluted net loss per share is computed using the weighted average number of common and potential common shares outstanding during the period. Potential common shares consist of shares issuable upon the exercise of stock options (using the treasury stock method). Options to purchase 5,339,825 and 4,835,881 shares of common stock were outstanding at September 30, 2007 and 2006, respectively, but have been excluded from the computation of diluted net loss per share because their effect was anti-dilutive.

#### **Note 3 - Share-Based Compensation:**

The components of share-based compensation recognized in the company's statements of operations for the three months ended September 30, 2007 and since inception are as follows:

	Three Months ended September 30,				Period From Inception (April 19, 1991) through September 30,			
		2007	•	2006	_	2007		
Research and development	\$	308,000	\$	468,000	\$	5,323,000		
General and administrative	_	369,000		285,000		5,617,000		
Total share-based compensation	\$ <sub>=</sub>	677,000	\$	753,000	\$	10,940,000		

The following table summarizes the company's stock option activity for the three months ended September 30, 2007:

		Options Outstanding						
				Weighted				
	Shares			Average				
	Available			Exercise				
	for Grant	Number	_	Price				
Balance at June 30, 2007	632,619	5,589,114	\$	10.98				
Options granted	(82,632)	82,632		2.51				
Options exercised								
Options forfeited or expired	331,921	(331,921)		9.78				
Balance at September 30, 2007	881,908	5,339,825		10.92				

Employee Stock Purchase Plan. The company adopted an Employee Stock Purchase Plan (the "Purchase Plan") in August 1995. Qualified employees may elect to have a certain percentage of their salary withheld to purchase shares of the company's common stock under the Purchase Plan. The purchase price per share is equal to 85% of the fair market value of the stock on specified dates. There were no sales under the Purchase Plan in the three month periods ended September 30, 2007 and 2006. Shares available for future purchase under the Purchase Plan are 260,807 at September 30, 2007.

#### Note 4 - Comprehensive Loss

Comprehensive loss includes net loss and unrealized gains (losses) on marketable securities that are excluded from the results of operations.

The company's comprehensive losses were as follows:

				ths Ended aber 30,
		2007		2006
Net loss	\$	(6,830,000)	\$	(6,491,000)
on available-for-sale securities	_	(3,000)	_	93,000
Comprehensive loss	\$_	(6,833,000)	\$_	(6,398,000)

#### Note 5 – Income Taxes

We adopted the provisions of Financial Accounting Standards Board ("FASB") Interpretation No. 48, *Accounting for Uncertainty in Income Taxes-an interpretation of FASB Statement No. 109* ("FIN 48"), on January 1, 2007. FIN 48 clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with SFAS No. 109, *Accounting for Income Taxes*, and prescribes a recognition threshold and measurement process for financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. Based on our evaluation, we have concluded that there are no significant uncertain tax positions requiring recognition in our financial statements. We may from time to time be assessed interest or penalties by major tax jurisdictions, although there have been no such assessments historically, with no material impact to our financial results. In the event we receive an assessment for interest and/or penalties, it would be classified in the financial statements as income tax expense. As of July 1, 2007 open tax years in major jurisdictions date back to 1991 due to the taxing authorities' ability to adjust operating loss carry forwards. The Company does not anticipate a material change to its total amount of unrecognized tax benefits within the next 12 months.

#### **Note 6 – Recent Accounting Pronouncements**

In September 2006, the FASB issued Statement of Financial Accounting Standards No. 157 (SFAS No. 157), "Fair Value Measurements" which clarifies the principle that fair value should be based on the assumptions market participants would use when pricing an asset or liability and establishes a fair value hierarchy that prioritizes the information used to develop those assumptions. Under the standard, fair value measurements would be separately disclosed by level within the fair value hierarchy. SFAS No. 157 is effective the first quarter of our 2008 fiscal year with early adoption permitted. The adoption of SFAS No. 157 did not have a material impact on our results from operations or financial position.

In June 2007, the FASB ratified EITF Issue No. 07-3 ("EITF 07-3"), *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities*. The scope of EITF 07-3 is limited to nonrefundable advance payments for goods and services to be used or rendered in future research and development activities pursuant to an executory contractual arrangement. This issue provides that nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities should be deferred and capitalized. Such amounts should be recognized as an expense as the related goods are delivered or the related services are performed. EITF 07-3 is effective for fiscal years beginning after December 15, 2007. Earlier application is not permitted. Companies should report the effects of applying this issue prospectively for new contracts entered into on or after the effective date of this issue. We are currently evaluating the impact of this standard on our results of operations and our financial position.

## Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion and analysis of our financial condition and results of operations together with our interim financial statements and the related notes appearing at the beginning of this report. The interim financial statements and this Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the financial statements and notes thereto for the year ended June 30, 2007 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on September 13, 2007.

The following discussion contains forward-looking statements that involve risks and uncertainties. These statements relate to future events, such as our future clinical and product development, financial performance and regulatory review of our product candidates. Our actual results could differ materially from any future performance suggested in this report as a result of various factors, including those discussed in Part II, Item IA, "Risk Factors", and elsewhere in this report, in the company's Annual Report on Form 10-K for the fiscal year ended June 30, 2007 and in our other Securities and Exchange Commission reports and filings. All forward-looking statements are based on information currently available to Pharmacyclics; and we assume no obligation to update such forward-looking statements. Stockholders are cautioned not to place undue reliance on such statements.

#### Overview

Pharmacyclics is a pharmaceutical company focused on the development of products that improve existing therapeutic approaches to cancer and other diseases. To date, substantially all of our resources have been dedicated to the research and development of our products, and we have not generated any commercial revenues from the sale of our products. We do not expect to generate any product revenues until we receive the necessary regulatory and marketing approvals and launch one of our products, if at all.

We have incurred significant operating losses since our inception in 1991, and as of September 30, 2007, had an accumulated deficit of approximately \$322.0 million. The process of developing and commercializing our products requires significant research and development, preclinical testing and clinical trials, manufacturing arrangements as well as regulatory and marketing approvals. These activities, together with our general and administrative expenses, are expected to result in significant operating losses until the commercialization of our products generates sufficient revenues to cover our expenses. We expect that losses will fluctuate from quarter to quarter and that such fluctuations may be substantial. Our achieving profitability depends upon our ability, alone or with others, to successfully complete the development of our products under development, obtain required regulatory approvals and successfully manufacture and market our products.

Xcytrin, our lead product candidate, is an anti-cancer drug being evaluated in various clinical trials. Based on the clinical activity seen in our initial Phase 3 trial in a subset of patients with brain metastases from non-small cell lung cancer (NSCLC), we conducted a pivotal Phase 3 clinical trial to confirm the potential clinical benefits observed in patients with brain metastases from non-small cell lung cancer. This trial, known as the **SMART** (Study of Neurologic Progression with **Motexafin** Gadolinium **And Radiation Therapy**) trial, enrolled 554 patients with brain metastases from non-small cell lung cancer. The SMART trial was designed to compare the safety and efficacy of whole brain radiation therapy (WBRT) alone to WBRT plus Xcytrin. The primary endpoint for the study was time to neurologic progression (TNP) as determined by a blinded events review committee.

In December 2006, we submitted a New Drug Application (NDA) to the Food and Drug Administration (FDA) for the use of Xcytrin in combination with radiation therapy for the treatment of patients with brain metastases from NSCLC. In February 2007, we received a refuse to file letter from the FDA citing failure to demonstrate statistically significant differences between treatment arms in the primary endpoint of the pivotal study to support approval. In the pivotal SMART trial, investigators found that patients given Xcytrin in addition to WBRT had a median time to neurologic progression of 15.4 months, compared to 10.0 months for patients who received only WBRT (p=0.12, hazard ratio=0.78), a trend in favor of Xcytrin. In April 2007, we requested that the FDA file our NDA over protest. File over protest is a procedure permitted by FDA regulations, which allows sponsors to have their NDA filed and reviewed when there is disagreement over the acceptability of the NDA. In April 2007, we announced that the FDA had filed our NDA. The Prescription Drug User Fee Act (PDUFA) date for completion of review by FDA is December 31, 2007. We do not anticipate presenting to an FDA oncology drug advisory committee (ODAC) meeting prior to our PDUFA date. The FDA has also designated Xcytrin as an orphan drug for the treatment of brain metastases arising from solid tumors.

We also are evaluating Xcytrin for the treatment of a diverse range of cancer types and in various clinical situations including Xcytrin as a single agent and in combination with chemotherapy and/or radiation therapy. One of Xcytrin's chemical features allows it to be visualized in the body using standard magnetic resonance imaging (MRI) procedures. Using MRI, we have established that Xcytrin localizes selectively in cancers. We own the worldwide rights to Xcytrin.

We are also developing several other oncology drugs. PCI-24781 is a novel compound that inhibits all isoforms of HDAC enzymes. In the cell nucleus, DNA is present with proteins as part of a tightly compacted complex called chromatin. HDAC enzymes play a role in modifying the structure of chromatin, allowing DNA transcription – a process by which DNA controls cellular activity – to occur. HDAC inhibitors appear to alter the transcription process. HDAC inhibitors target tumors through multiple mechanisms, and laboratory studies have shown that they can prompt cells to stop growing or die. This may happen through the expression of tumor suppressor genes, the prevention of angiogenesis, and the targeting of various critical proteins.

PCI-24781 is now in a Phase 1 trial in patients with advanced solid tumors. The objective of the trial is to determine the drug's safety and tolerability, when given intravenously, and also to assess absorption and plasma levels of the drug following oral administration. Studies indicate that PCI-24781 achieves sustained plasma levels following oral administration. We believe PCI-24781 has desirable potency and pharmacokinetic properties, which may provide clinical advantages.

Laboratory studies also demonstrate that PCI-24781 inhibits homologous recombination, a cellular mechanism of DNA repair. These data suggest that PCI-24781 could be used successfully in combination with other cancer therapies that generate DNA damage repaired by homologous recombination, such as gamma-irradiation, cisplatin, and certain other chemotherapy drugs.

An HDAC-8 selective inhibitor is now in preclinical testing. We believe that this compound may exhibit more selectivity for certain types of cancer and may be useful for treatment of inflammatory and autoimmune diseases.

PCI-24783 is a small molecule inhibitor of Factor VIIa. This molecule selectively inhibits Factor VIIa when it is complexed with a protein called tissue factor (TF). In cancer, the Factor VIIa:TF complex is found in abundance in pancreatic, gastric, colon and other tumors, and triggers a host of physiologic processes that facilitate tumor angiogenesis, growth and invasion. Laboratory studies and animal models indicate that inhibitors of Factor VIIa may block tumor growth and metastasis. We are conducting the required preclinical safety studies to support the potential filing of an Investigational New Drug (IND) application with the FDA.

PCI-32765 is a small molecule tyrosine kinase inhibitor. When immune cells called B-lymphocytes are overactive, the immune system produces inflammatory cells and antibodies that begin to attack the body's own tissue, leading to autoimmune diseases such as rheumatoid arthritis. We are developing compounds that can inhibit an enzyme, known as Btk, which is

required for early B-cells to mature into fully functioning cells. In published studies, these compounds have demonstrated a dose dependent ability to inhibit disease development in rheumatoid arthritis animal models. Recent studies have shown that these compounds may inhibit the proliferation of lymphoma cells, or malignancies involving B-cells, indicating their potential for treatment of certain lymphomas and leukemias. We are conducting the required preclinical safety studies to support the potential filing of an IND application with the FDA.

We are subject to risks common to pharmaceutical companies developing products, including risks inherent in our research, development and commercialization efforts, preclinical testing, clinical trials, uncertainty of regulatory and marketing approvals, uncertainty of market acceptance of our products, history of and expectation of future operating losses, reliance on collaborative partners, enforcement of patent and proprietary rights, and the need for future capital. In order for a product to be commercialized, we must conduct preclinical tests and clinical trials, demonstrate efficacy and safety of our product candidates to the satisfaction of regulatory authorities, obtain marketing approval, enter into manufacturing, distribution and marketing arrangements, build a U.S. commercial oncology franchise, obtain market acceptance and, in many cases, obtain adequate coverage of and reimbursement for our products from government and private insurers. We cannot provide assurance that we will successfully develop our drug candidates and obtain the necessary regulatory and marketing approvals to generate revenues or achieve and sustain profitability in the future.

### **Results of Operations**

#### Revenues

	П	ree Month	s ended		
		Septembe	r 30,	Percent	
	20	007	2006	change	
Contract and grant revenues	\$	\$	19,000		

The decrease in contract and grant revenues for the three ended September 30, 2007 is the result of the completion of work associated with a federal grant awarded by the National Institutes of Health (NIH) in fiscal 2007.

#### Research and Development

	Three Mo		
	Septer	Percent	
	 2007	2006	change
Research and development expenses	\$ 5,240,000	\$ 5,078,000	3%

The increase of 3% or \$162,000 in research and development expenses for the three months ended September 30, 2007 as compared to the three months ended September 30, 2006 was primarily due to an increase of \$838,000 in drug manufacturing costs associated with our HDAC, Factor VIIa and Btk programs, and \$677,000 in preclinical costs related to our Factor VIIa program, partially offset by a reduction of \$943,000 in personnel costs due to lower headcount and a reduction of \$250,000 in consulting costs.

We expect research and development expenses in our fiscal second quarter to increase slightly as compared to our fiscal first quarter.

Research and development costs are identified as either directly attributed to one of our research and development programs or as an indirect cost, with only direct costs being tracked by specific program. Direct costs consist of personnel costs directly associated with a program, preclinical study costs, clinical trial costs, and related clinical drug and device development and manufacturing costs, drug formulation costs, contract services and other research expenditures. Indirect costs consist of personnel costs not directly associated with a program, overhead and facility costs and other support service expenses. The following table summarizes our principal product development initiatives, including the related stages of development for each product, the direct costs attributable to each product and total indirect costs for each respective period. The information in the

column labeled "Estimated Completion of Phase" is only our estimate of the timing of completion of the current in-process development phase. The actual timing of completion of those phases could differ materially from the estimates provided in the table. For a discussion of the risks and uncertainties associated with the timing and cost of completing a product development phase, see Part II, Item IA, "Risk Factors."

Prior to fiscal 1999, we did not track our research and development expenses by specific program and for this reason we cannot accurately estimate our total historical costs on a specific program basis. Direct costs by program and indirect costs are as follows:

Related R&D Expenses

			Estimated		Three M	Months ended ember 30,			
Program	Description	Phase of  Development	Completion of Phase	2007			2006		
XCYTRIN	Cancer	Several Phase 1 trials Several Phase 2 trials Phase 3	Unknown Unknown Fiscal 2006	\$	977,000	\$	2,265,000		
HDAC Inhibitors	Cancer	Phase 1	Unknown		909,000		382,000		
Btk Inhibitors	Lymphomas and autoimmune diseases	Preclinical	Unknown		595,000				
Factor VIIa Inhibitor	Cancer	Preclinical	Unknown	_	1,071,000	_			
	Total direct costs				3,552,000		2,647,000		
	Indirect costs				1,688,000		2,431,000		
	Total research and								
	development expenses			\$	5,240,000	\$	5,078,000		

## General and Administrative

		Three Mo	nth	s ended		
	September 30,			Percent		
	. =	2007		2006	change	_
General and administrative expenses	\$	2,067,000	\$	1,924,000	7%	

The increase of 7% or \$143,000 in general and administrative expenses for the three months ended September 30, 2007 as compared to the three months ended September 30, 2006 was primarily due to a \$272,000 increase in corporate communication expenses.

We expect general and administrative expenses in our fiscal second quarter to be approximately the same as in our fiscal first quarter.

#### Interest and Other, Net

		Three Mo	nth	sended		
		September 30,			Percent	
	=	2007	_	2006	change	
Interest and other, net	\$	477,000	\$	492,000	-3%	

Interest and other, net did not change significantly between the first quarter of fiscal 2008 and the same period in fiscal 2007 as our investment balances and interest rates were similar in the two periods. Our cash equivalents and marketable securities consist primarily of fixed rate instruments.

#### **Liquidity and Capital Resources**

Our principal sources of working capital have been private and public equity financings and proceeds from collaborative research and development agreements, as well as interest income.

As of September 30, 2007, we had approximately \$32,323,000 in cash, cash equivalents and marketable securities. Net cash used in operating activities of \$6,498,000 during the three months ended September 30, 2007, resulted primarily from our net loss, net of depreciation and amortization, share-based compensation expense and a decrease in accrued liabilities.

Net cash provided by investing activities of \$2,976,000 in the three months ended September 30, 2007 consisted primarily of maturities and sales of marketable securities.

Net cash provided by financing activities was \$0 in the three months ended September 30, 2007.

In August 2006, we entered into a common stock purchase agreement with Azimuth Opportunity Ltd., which provides that, upon the terms and subject to the conditions set forth in the purchase agreement, Azimuth is committed to purchase, at our discretion, up to \$20.0 million of our common stock, or 4,189,337 shares, whichever occurs first, at a discount of 5% to 7%, to be determined based on our market capitalization at the start of each sale period. The term of the purchase agreement is 18 months. Upon each sale of our common stock to Azimuth under the purchase agreement, we have also agreed to pay Reedland Capital Partners a placement fee equal to one percent of the aggregate dollar amount of common stock purchased by Azimuth. Azimuth is not required to purchase our common stock if the price of our common stock falls below \$3.00 per share. To date, we have not sold any stock to Azimuth.

In November 2006, we completed a public offering of common stock and sold 4,830,000 shares of common stock at a price of \$4.75 per share for net proceeds of approximately \$21,300,000. In February 2007, we filed a registration statement on Form S-3 to offer and sell, from time to time, equity, debt securities and warrants in one or more offerings up to a total dollar amount of \$100 million. We may seek to raise funds through additional public offerings in the future but cannot guarantee that such efforts will be successful.

Our future contractual obligations at September 30, 2007 are as follows:

	Operating Lease Commitments	
	-	
Remaining 9 months of fiscal 2008	\$ 714,000	
Fiscal 2009	946,000	
Fiscal 2010	487,000	
Total	\$ 2,147,000	

In April 2006, we acquired multiple small molecule drug candidates for the treatment of cancer and other diseases from Celera Genomics, an Applera Corporation business. Future milestone payments under the agreement could total as much as \$144 million, although we currently cannot predict if or when any of the milestones will be achieved. In addition, Celera will also be entitled to royalty payments in the mid- to high single digits based on annual sales of any drugs commercialized from these programs.

Based upon the current status of our product development and commercialization plans, we believe that our existing cash, cash equivalents and marketable securities will be adequate to satisfy our capital needs through at least the next twelve months. We expect research and development expenses, as a result of on-going and future clinical trials, to consume a large portion of our existing cash resources. Changes in our research and development plans or other changes affecting our operating expenses may affect actual future consumption of existing cash resources as well. In any event, we will need to raise substantial additional capital to fund our operations in the future. We expect to finance our future cash needs through public or private financings, collaborative relationships (partnerships with other drug manufacturers) or other arrangements to complete commercialization. Our actual capital requirements will depend on many factors, including the following:

- the progress and success of clinical trials of our product candidates;
- the costs and timing of obtaining regulatory approvals;
- our ability to establish and the scope of any new collaborations; and
- the timing and scope of commercialization expenses for Xcytrin.

Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially. The factors described above will impact our future capital requirements and the adequacy of our available funds. If we are required to raise additional funds, we cannot be certain that such additional funding will be available on terms attractive to us, or at all. Furthermore, any additional equity financing may be dilutive to existing stockholders and debt financing, if available, may involve restrictive covenants. Collaborative arrangements, if necessary to raise additional funds, may require us to relinquish rights to certain of our technologies, products or marketing territories. Our failure to raise capital when needed could have a material adverse effect on our business, financial condition and results of operations.

#### **Off-Balance Sheet Arrangements**

We do not have any off-balance sheet arrangements that have or are reasonably likely to have a current or future material effect on our financial condition, changes in our financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources.

#### Critical Accounting Policies, Estimates and Judgments

This discussion and analysis of financial condition and results of operations is based upon our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosures. On an on-going basis, we evaluate our estimates, including those related to revenue recognition and clinical trial accruals. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results, however, may differ significantly from these estimates under different assumptions or conditions and may adversely affect the financial statements.

We believe the following critical accounting policies reflect the more significant judgments and estimates used in the preparation of our financial statements and accompanying notes.

#### Revenue Recognition

Revenues are recognized when persuasive evidence of an arrangement exists, title has transferred or services have been rendered, the price is fixed and determinable and collectibility is reasonably assured. License revenue is typically recognized

over the term of the arrangement and milestone revenue is recognized when earned as evidenced by achievement of the specified milestone and the absence of any on-going obligation. License, milestone, contract and grant revenues are not subject to repayment. Any amounts received in advance of performance are recorded as deferred revenues.

#### Cash Equivalents and Marketable Securities

We maintain investment portfolio holdings of various issuers, types and maturities. We consider all highly liquid investments purchased with original maturities of three months or less to be cash equivalents. At September 30, 2007, all other investment securities are classified as available-for-sale and consequently are recorded on the balance sheet at fair value with unrealized gains and losses reported as a component of accumulated other comprehensive income (loss) within stockholders' equity. Management assesses whether declines in the fair value of investment securities are other than temporary. If the decline in fair value is judged to be other than temporary, the cost basis of the individual security is written down to fair value and the amount of the write down is included in earnings. In determining whether a decline is other than temporary, management considers the following factors:

- Length of the time and the extent to which the market value has been less than cost;
- The financial condition and near-term prospects of the issuer; and
- Our intent and ability to retain our investment in the issuer for a period of time sufficient to allow for any anticipated recovery in market value.

To date we have had no declines in fair value that have been identified as other than temporary.

#### Research and Development Expenses and Accruals

Research and development expenses include personnel and facility-related expenses, outside contracted services including clinical trial costs, manufacturing and process development costs, research costs and other consulting services. Research and development costs are expensed as incurred. In instances where we enter into agreements with third parties for clinical trials, manufacturing and process development, research and other consulting activities, costs are expensed upon the earlier of when non-refundable amounts are due or as services are performed. Amounts due under such arrangements may be either fixed fee or fee for service, and may include upfront payments, monthly payments, and payments upon the completion of milestones or receipt of deliverables.

Our cost accruals for clinical trials are based on estimates of the services received and efforts expended pursuant to contracts with numerous clinical trial centers and clinical research organizations. In the normal course of business we contract with third parties to perform various clinical trial activities in the on-going development of potential products. The financial terms of these agreements are subject to negotiation and vary from contract to contract and may result in uneven payment flows. Payments under the contracts depend on factors such as the achievement of certain events, the successful enrollment of patients, the completion of portions of the clinical trial or similar conditions. The objective of our accrual policy is to match the recording of expenses in our financial statements to the actual services received and efforts expended. As such, expense accruals related to clinical trials are recognized based on our estimate of the degree of completion of the event or events specified in the specific clinical study or trial contract.

#### Share-Based Compensation

We adopted SFAS 123R, *Share-Based Payments*, effective beginning July 1, 2005 using the modified prospective application transition method. The modified prospective application transition method requires that companies recognize compensation expense on new share-based payment awards and existing share-based payment awards that are modified, repurchased, or cancelled after the effective date. Additionally, compensation cost of the portion of awards of which the requisite service has not been rendered that are outstanding as of the July 1, 2005 shall be recognized as the requisite service is rendered.

The fair value of each stock option is estimated on the date of grant using the Black-Scholes valuation model. Expected volatility is based on historical volatility data of the company's stock. The expected term of stock options granted is based on historical data and represents the period of time that stock options are expected to be outstanding. The expected term is calculated for and applied to one group of stock options as the company does not expect substantially different exercise or post-

vesting termination behavior amongst its employee population. The risk-free interest rate is based on a zero-coupon United States Treasury bond whose maturity period equals the expected term of the company's options.

#### Item 3. Quantitative and Qualitative Disclosures About Market Risk

Our exposure to interest rate risk relates primarily to our investment portfolio. Fixed rate securities may have their fair market value adversely impacted due to fluctuations in interest rates, while floating rate securities may produce less income than expected if interest rates fall. Due in part to these factors, our future investment income may fall short of expectations due to changes in interest rates or we may suffer losses in principal if forced to sell securities that have declined in market value due to changes in interest rates. The primary objective of our investment activities is to preserve principal while at the same time maximizing yields without significantly increasing risk. To achieve this objective, we invest in debt instruments of the U.S. Government and its agencies and high-quality corporate issuers, and, by policy, restrict our exposure to any single corporate issuer by imposing concentration limits. To minimize the exposure due to adverse shifts in interest rates, we maintain investments at an average maturity of generally less than two years. Assuming a hypothetical increase in interest rates of one percentage point, the fair value of our total investment portfolio as of September 30, 2007 would have declined by approximately \$129,000.

#### Item 4. Controls and Procedures

- (a) Evaluation of disclosure controls and procedures: As required by Rule 13a-15 under the Securities Exchange Act of 1934, as of the end of the first fiscal quarter of 2008, we carried out an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures. This evaluation was carried out under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer. Based upon that evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures are adequate and effective to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized, and reported, within the time periods specified in the Securities and Exchange Commission's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in our reports filed under the Exchange Act is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.
- (b) Changes in internal controls over financial reporting: There has been no change in our internal control over financial reporting during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal controls over financial reporting.

#### PART II. OTHER INFORMATION

Item 1. Legal Proceedings

Not Applicable.

Item 1A. Risk Factors

In addition to the other information set forth in this report, you should carefully consider the factors discussed in Part I, "Item 1A. Risk Factors" in our Annual Report on Form 10-K for the fiscal year ended June 30, 2007, which have not materially changed other than as set forth below. Those risks, which could materially affect our business, financial condition or future results, are not the only risks we face. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results.

To generate revenue, we will depend on FDA approval of our lead product candidate, Xcytrin for the potential treatment of non-small cell lung cancer patients with brain metastases. If we are unable to obtain FDA approval, our ability to generate revenue will be significantly delayed.

Our ability to generate revenue will depend on the successful development, regulatory approval and commercialization of Xcytrin. In December 2005, we announced the top line results of our pivotal Phase 3 clinical study of Xcytrin for the potential treatment of non-small cell lung cancer (NSCLC) patients with brain metastases. Although patients receiving Xcytrin had a

longer time to neurologic progression (TNP), the study's primary endpoint, the difference compared to patients in the control arm did not reach statistical significance.

Based on our review of the data from the SMART trial, in December 2006 we submitted a New Drug Application (NDA) to the FDA for the potential treatment of NSCLC patients with brain metastases. In meetings with FDA in early 2006, FDA noted that the applicable review Division has not approved drugs based on the results of non-pre-specified subgroup analyses when the trial has failed to meet its primary endpoint. FDA discouraged the submission of an NDA based on subset analyses from the SMART trial. However, in subsequent meetings with FDA and further review of the data, the Agency indicated a willingness to review an NDA based on analyses which include all of the data.

In February 2007, we received a refuse to file letter from the FDA citing failure to demonstrate statistically significant differences between treatment arms in the company's trials. In April 2007, we requested that the FDA file our NDA over protest. File over protest is a procedure permitted by FDA regulations, which allows sponsors to have their NDA filed and reviewed when there is disagreement over the acceptability of the NDA. On April 23, 2007, we announced that the FDA had filed our NDA. The Prescription Drug User Fee Act (PDUFA) date for completion of review by FDA is December 31, 2007.

The FDA's Division of Drug Oncology Products often requests that an outside advisory panel review aspects of a sponsor's NDA. While we believe that our NDA qualifies for such a review, we do not anticipate presenting to an FDA oncology drug advisory committee (ODAC) meeting prior to our PDUFA date.

The FDA could also require that we conduct additional studies and submit that data before it will approve our application, which would require us to expend more resources than we planned or than are available to us, and could substantially delay any approval of our application. The FDA has indicated that it is not satisfied with data included in our NDA, and we may need to expend additional resources or conduct additional studies, including clinical trials, to obtain data that the FDA believes is sufficient to support approval. It is also possible that additional studies may not result in approval of our application. Even though the FDA has accepted our NDA for filing over protest, there can be no assurance that it will be approved in a timely manner or at all.

#### We have a history of operating losses and we expect to continue to have losses in the future.

We have incurred significant operating losses since our inception in 1991 and, as of September 30, 2007, had an accumulated deficit of approximately \$322.0 million. We expect to continue to incur substantial additional operating losses until such time, if ever, as the commercialization of our products generates sufficient revenues to cover our expenses. Our achieving profitability depends upon our ability, alone or with others, to successfully complete the development of our products, and to obtain required regulatory approvals and to successfully manufacture and market our proposed products. If our lead product, Xcytrin, fails to receive regulatory approval on a timely basis, or at all, our ability to become profitable would be materially impacted. To date, we have not generated revenue from the commercial sale of our products.

- Item 2. Unregistered Sales of Equity Securities and Use of Proceeds Not Applicable.
- Item 3. Defaults Upon Senior Securities
  - Not Applicable.
- Item 4. Submission of Matters to a Vote of Security Holders

Not Applicable.

Item 5. Other Information

Not Applicable.

Item 6. Exhibits

- 3.1 Amended and Restated Bylaws of Pharmacyclics, Inc. (Incorporated by reference to Exhibit 3.2 to the Quarterly Report on Form 10-Q for the quarter ended December 31, 2001).
- 3.2 Amendment to Amended and Restated Bylaws of Pharmacyclics, Inc., dated September 17, 2007.
- 31.1 Rule 13a-14(a)/15d-14(a) Certification of CEO.
- 31.2 Rule 13a-14(a)/15d-14(a) Certification of CFO.
- 32.1 Section 1350 Certifications of CEO and CFO.

# **Signatures**

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

	Pharmacyclics, Inc.
	(Registrant)
Dated: October 31, 2007	By: /s/ RICHARD A. MILLER, M.D.
	Richard A. Miller, M.D.  President and Chief Executive Officer
Dated: October 31, 2007	By:/s/ LEIV LEA
	Leiv Lea  Vice President, Finance and Administration and Chief Financial Officer and Secretary

# **EXHIBITS INDEX**

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